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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/142,043	12/01/1998	DANUTA EWA IRENA MOSSAKOWSKA	88362/104	1645

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EXAMINER	
HAMUD, FOZIA M	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Application No.	Applicant(s)
09/142,043	MOSSAKOWSKA et al.
Examiner	**Art Unit**
Fozia Hamud	1647

Office Action Summary

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 13, 2003*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *37-57* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☒ Claim(s) *37, 38, 51, and 53-56* is/are allowable

6) ☒ Claim(s) *39-50, 52, and 57* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's after final amendment filed on 13 February 2003 in Paper No.34 has been entered. Claims 37-49, 51-57 have been amended. Claims 37-57 are pending and are under consideration by the Examiner.

2. Upon reconsideration, the prosecution on the merits of this application is reopened and the finality of the rejection of the previous office action is withdrawn.

3. The following previous rejections and objections are withdrawn in light of Applicants amendments filed in Paper No.35, 02/13/03:

(I) The rejection of claims 37-57, made under 35 U.S.C. 112, second paragraph, for reciting " an SCR3-derived polypeptide".

4. ***Maintenance of previous Rejections:***

4a. Claims 39, 42 stand rejected under 35 U.S.C. 112, second paragraph for reciting ".....chemically reactive amino acid residue...", for reasons of record set forth in the office action mailed on 22 October 2002 in paper No:32, pages 3-4. Appropriate correction is requires.

New Rejections:

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5a. Claim 57 is rejected under 35 U.S.C. 112, first paragraph, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled

in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 57 encompasses a pharmaceutical composition comprising a therapeutically effective amount of a polypeptide having a partial sequence from short consensus repeat 3 of complement receptor 1, wherein the polypeptide comprises a 6 to 23 amino acid portion of SEQ ID NO:1, wherein the polypeptide has at least amino acid residues 6-11 or amino acid residues 11-20 of SEQ ID NO:1. Thus the claim encompasses a "pharmaceutical use" for the composition. For the claim to be enabled, the specification must teach how to use the composition for at least one pharmaceutical use without undue experimentation. Steadman's Medical Dictionary (24th Edition, 1982) defines "drug" as "a therapeutic agent; any substance other than food, used in the prevention, diagnosis, alleviation, treatment or cure of disease in man and animal." Ansel et al. (Pharmaceutical Dosage Forms and Drug Delivery Systems, Seventh Edition), says "A drug is defined as an agent intended for use in the diagnosis, mitigation, treatment, cure or prevention of disease in humans or in other animals. One of the most astounding qualities of drugs is the diversity of their actions and effects on the body." The following are examples of "pharmaceutical uses": administering vitamin supplements (preventing disease); using labeled antibodies for in vivo imaging (diagnosing disease); administering a substance to alleviate a symptom of a disease (alleviating or treating disease); and administering an antibiotic (curing bacterial infection). Administering a polypeptide to produce antibodies to protect the individual from contracting a disease, i.e., vaccination, is a pharmaceutical use, however, administering a polypeptide to produce antibodies which are then collected from the animal and used in various ways is not a pharmaceutical use.

In the present situation, to enable a pharmaceutical use for the polypeptide having a partial sequence from short consensus repeat 3 of complement receptor 1, wherein the polypeptide comprises a 6 to 23 amino acid portion of SEQ ID NO:1, wherein the polypeptide has at least amino acid residues 6-11 or amino acid residues 11-20 of SEQ ID NO:1, requires the specification to teach how to use the substance, without undue experimentation, for the prevention, diagnosis, alleviation, treatment or cure of a disease in the animal to which the substance is administered. However, the specification does not provide adequate guidance as to how the claimed polypeptide can be used to treat or diagnose any disorders. The specification asserts that the polypeptide of the instant invention is useful in the treatment and diagnosis of many complement-mediated or complement related diseases and disorders, and lists a number of disparate diseases that can be treated or diagnosed using said polypeptide, including neural disorder, Parkinson's disease, Alzheimer's disease, etc (page 12, line 25 through page 15, line 19).

However, there are no examples of treatment by administration of the claimed polypeptide. There are a number of in vitro experiments showing that the claimed polypeptide has anti-complement activity measured by the hemolysis of sheep erythrocytes, (pages 22-23).

However, these experiments are directed to comparing the anti-hemolytic activities of different forms of the claimed polypeptide, for examples, Applicants have shown that increasing anti-hemolytic potency is correlated with an increase in the proportion of linear peptide, (see page 23, lines 8-12). There are no working examples of treatment of an animal for any disorder. It is not predictable from the in vitro experiments of the instant specification or from the teachings of the

prior art that the claimed polypeptide could be used to treat the diseases or disorders asserted in the specification.

Due to the lack of direction or guidance in the specification, the absence of working examples and teachings of the prior art, the unpredictability in the art, and the complex nature of the invention, undue experimentation would be required of the skilled artisan to use a "pharmaceutical composition" comprising a therapeutically effective amount of a polypeptide having a partial sequence from short consensus repeat 3 of complement receptor 1, wherein the polypeptide comprises a 6 to 23 amino acid portion of SEQ ID NO:1, wherein the polypeptide has at least amino acid residues 6-11 or amino acid residues 11-20 of SEQ ID NO:1. However, the specification enables the use of "a composition" comprising a polypeptide having a partial sequence from short consensus repeat 3 of complement receptor 1, wherein the polypeptide comprises a 6 to 23 amino acid portion of SEQ ID NO:1, wherein the polypeptide has at least amino acid residues 6-11 or amino acid residues 11-20 of SEQ ID NO:1 and a pharmaceutically acceptable carrier. Deletion of the word "pharmaceutical" before the word "composition" in claim 57 would obviate the rejection for this claim, since the specification has demonstrated that claimed polypeptide has anti-hemolytic activity which can be used in an in vitro system. However, pharmaceutical composition comprising a therapeutically effective amount of a polypeptide having a partial sequence from short consensus repeat 3 of complement receptor 1, wherein the polypeptide comprises a 6 to 23 amino acid portion of SEQ ID NO:1, wherein the polypeptide has at least amino acid residues 6-11 or amino acid residues 11-20 of SEQ ID NO:1 is not enabled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 39-50, 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6a. Claim 39 recites ".....,amino acid residue with a chemically reactive side chain..", however, there is an insufficient antecedent base for this phrase .

6b. Claim 42 recites "...., wherein the polypeptide is *altered* to remove amino acid residues with chemically reactive chains", however it is unclear how many amino acids to be altered or how to *alter* them. The metes and bounds of the claim can not be ascertained.

6c. Claims 43, 44 and 45 are vague and indefinite for reciting "*core structure*", because, it is unclear what is the actual structure of said core structure. Is the core structure part of the recited amino acid sequences, or is it from a different polypeptide that connects the multimeric constituents? Claim 43 is also vague for the recitation "at least", if the recited multimeric comprises more than two polypeptide constituents, then what are the other constituents, besides the recited sequences? Appropriate correction is requires.

6d. Claim 45 is also indefinite, because it is unclear whether the recited core structure is one of the three structures listed in the claim, or whether the core structure is some combination of them? Clarification is required.

6e. Claim 46 further limits the multimeric of claim 43, to a multimeric polypeptide which comprises "two to eight" polypeptides having only partial sequence from short consensus repeat 3 of complement receptor 1, however it is unclear exactly what the claimed multimeric comprises. The short consensus repeat 3 of complement receptor 1, comprises arginine 122 to lysine 196 of the full length complement receptor 1, (see SEQ ID NO:3 on page 17 of the instant specification). The multimeric recited in claim 43 is interpreted as comprising two polypeptide constituents that comprise 6 to 23 amino acid portion of SEQ ID NO:1, attached to a core structure. With respect to claim 46, it is unclear whether the multimeric further comprises other portions of the short consensus repeat 3 of complement receptor 1, and if so, which other amino acid residues should it comprise?

6f. Claim 47 is drawn to a multimeric polypeptide, however, it is unclear how the components of the multimeric are attached to one another. clarification of the claim is required.

6i. Claim 48 is vague and indefinite for reciting "non-essential regions of host protein", because it is unclear what said non essential region is, and instant specification provides no definition for said region. Appropriate correction is required.

6j. Claim 52 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the claim is drawn to a process for preparing a polypeptide, by condensing peptide units, however the claim lacks full positive recitation of method steps. Appropriate correction is required.

Claims 41, 47 and 50 are rejected under 35 U.S.C. 112, second paragraph, insofar as they depend on claims 39, 43 and 48 respectively,for the limitations set forth directly above.

Conclusion

7. Claims 37-38, 51, 53-56 are allowable.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wednesday-Thursday from 6:30AM to 4:00PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
03 June 2003

GARY KUNZ
SUPERVISORY PATENT EXAMINER
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